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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/709,795 | 05/28/2004 | Michael A. Slivka | 101896-0252 | 3794 |
| 21125 | 7590 | 03/21/2006 | EXAMINER | |
| NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 | | | SHAFFER, RICHARD R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/709,795

Applicant(s)

SLIVKA ET AL.

Examiner

Richard R. Shaffer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 13-16 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-12, 17-24 and 26-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings were received on March 2nd, 2006. These drawings are accepted by the examiner.

Specification

The corrected abstract was received on February 28th, 2006 and is accepted by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-12, 17-24, and 26-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Glascott (US Patent Application Publication 2002/0151900).

Glascott discloses a polyaxial screw comprising: a stainless steel or titanium (Page 1, Paragraph 0017) bone-engaging member (12) with a spherical head (16); U-shaped receiver member (22) seats both a spinal rod (34) and the spherical head of the bone-engaging member in a spaced apart relationship; and a set screw/nut (36) to lock the spinal rod in place while allowing the receiver to move freely relative to the bone-engaging member.

In regard to method claims 24 and 26-31, all structure recited is accounted for in the previous paragraph. As for implanting a plurality of anchoring devices into adjacent

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vertebrae in a spinal column, the background section (Column 1, Lines 10-18) of Glascott explains how polyaxial bone screws are used for connecting vertebrae to rods in spinal surgery.

Response to Arguments

Applicant's arguments filed February 2nd, 2006 have been fully considered but they are not persuasive.

In regard to arguments directed towards claims 1, 6-12, and 17-23, applicant asserts that Glascott does disclose a fastening element **adapted** to mate to the receiver member to lock a fixation element in a fixed position to the receiver member while allowing the receiver member to move freely relative to the bone-engaging member. Applicant is incorrect. Glascott clearly is "adapted" to mate in such a way as to lock the spinal rod in a fixed vertical and horizontal position within the receiver member while maintaining movement about the bone-engaging member. One would do so merely by not fully tightening the setscrew in place. Thus, Glascott is "adapted" to perform the function claimed.

In regard to claims 24 and 26-31, applicant states that Glascott does not disclose a method for correcting spinal deformities that includes locking a spinal fixation element to a receiver member on a plurality of anchoring devices to maintain vertebrae at a fixed distance relative to one another while allowing free movement of each vertebrae in the fixed position. Examiner previously broadly interpreted this statement because it is impossible for vertebrae to "feely move" while "fixed" with applicant's disclosed invention. Even if applicant intended such language to mean locked at a fixed axial

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distance along the spinal rod, the spinal fixation system would still restrict lateral displacement and not allow free motion. Further, in terms of pivotal motion, applicant's device is restricted to a fixed range of angles the device could pivot within, thus restricting movement of the vertebrae. The interpretation given to this set of claims was that there had to be some movement between adjacent vertebrae with the spinal system implanted. Glascott discloses a device that will inherently allow some vertebral motion even when the nut is locked tight, for example: imperfect gripping of components allowing slippage and rotation as well as rod flexing from a person bending or twisting.

In regard to arguments directed towards claims 32-35, applicant asserts that Glascott does not disclose, teach, or suggest a receiver member having a proximal and distal seat. The "pressure disk" (reference character 28) as applicant uses clearly has a proximal and distal seat, with the seats adapted for a spinal rod and bone screw head respectively. Further, the pressure disk can be treated as a portion of the "receiver" and has been by the examiner.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard Shaffer

Richard Shaffer
March 9th, 2006


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER